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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,259	02/14/2006	Michael Schutz	DEBE:046US	3637

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,259	SCHUTZ ET AL.	
	Examiner	Art Unit	
	MARSHA M. TSAY	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *04 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to Applicants' remarks received December 4, 2004. Claim 6 is canceled. Claims 1-5, 7-18 are pending and currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

On page 6 of the previous Office action (mailed October 29, 2007), the action was inadvertently noted to be a final action. However, the action of October 29, 2007 was intended to be a non-final Office action, which was correctly indicated on the PTOL-326 (office action summary) form.

Priority: The instant application claims foreign priority to June 24, 2002.

The declaration under 37 CFR 1.132 filed December 4, 2007 is insufficient to overcome the rejection of claims 1-5, 7-12, 14-17 based upon indefiniteness under 35 U.S.C. 112, second paragraph; Suzuki et al. under 35 U.S.C. 102(b); Baxa et al. under 35 U.S.C. 102(b) as set forth in the last Office action because: while the declaration sets forth a general understanding of "p12-similar bacteriophage tail protein", there is no specific definition provided for "p12-similar".

Objections and Rejections

Claim 4 is objected to because of the following informalities: claim 4(a) line 3 recites "directed". It is unclear if by "directed", the claim meant to recite "directly" or "specifically". Appropriate correction or further clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-12, 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4 recite p12-similar bacteriophage tail protein. The claims are indefinite because it there is no clear definition of what a "p12-similar" bacteriophage tail protein is, i.e. what is the degree of similarity, similarity in binding, function, structure, etc. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 2-3, 5, 7-12, 14-17 are included in this rejection because they are dependent on the above claims and fail to cure the defect.

In their remarks, Applicants assert that it was known before the priority date of the present application that bacteriophage tail fibers, especially the ones similar to p12, are often involved in host cell recognition and were suggested to bind to parts of the lipopolysaccharides on the bacterial surface. Applicants disclose a table of p12 like proteins before and after the priority date of the instant application. Applicants further submit the declaration of Dr. Miller,

which sets forth that there is a general understanding in the field that "p12-similar" would be understood as a tail fiber that binds to highly conserved regions of endotoxin and exhibit substantial sequence homology to T4p12. Applicant's arguments have been fully considered but they are not persuasive.

As noted in the 35 U.S.C. 112, 2nd paragraph, rejection above, the term "similar" is a term of degree. When the term "similar" is directed to a p12 bacteriophage tail protein, it is unclear what Applicants intended to cover by the recitation of "p12-similar" bacteriophage tail protein, i.e. what is the degree of similarity, similarity in binding, function, structure, etc. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Neither the remarks nor the instant specification appear to disclose a specific definition of what is meant by "p12-similar." Most of the "p12 like" proteins submitted by Applicants have a submission date after the instant priority date and are disclosed to have an amino acid identity in the range between 34-62%. Since it is unclear what is intended to be covered by "p12-similar", there could be many different proteins having a sequence identity of greater than 30% that may or may not bind to endotoxin. It is not clear what the degree of similarity should or can be, i.e. how great or how less, and to which characteristic and/or property of the protein that the "similarity" resides. Therefore, the term "similar" renders the instant claims indefinite because it is not clear what is intended to be covered by "p12-similar" bacteriophage tail protein.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 11, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (1999 Virus Research 60: 95-99; previously cited). For examination purposes, "p-12 similar" has been given its broadest meaning and can encompass any bacteriophage tail protein.

Suzuki et al. disclose the specific interaction of fused H protein of bacteriophage ϕX174 with receptor lipopolysaccharides (LPS). Various concentrations of HisH (histidine-tagged H protein) were adsorbed onto 96 flat-bottom wells, rinsed, and incubated with a sample of biotinylated LPS (p. 97 col. 2; claims 1, 11). The wells were washed to remove unbound LPS, and then added with streptavidin-peroxidase complex (p. 98 col. 1; claims 2). The bound biotinylated LPSs were detected at absorbance of 490 nm (p. 98 Fig. 3; claims 2-3, 15). In Figure 3, Suzuki et al. teach the dose-dependent binding of biotinylated LPS from *E. coli* to HisH (histidine-tagged H protein) (p. 98; claims 1, 3, 11, 15). Suzuki et al. disclose a first assay measuring phage ϕX174 activity of biotinylated LPSs were incubated in Tris-HCl buffer, NaCl, $MgSO_4$, and $CaCl_2$ with the biotinylated LPSs (p. 97 col. 2). Suzuki et al. do not explicitly teach His-tagged phage ϕX174 is incubated with divalent ions with LPSs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the buffer system including Tris-HCl buffer, NaCl, $MgSO_4$, and $CaCl_2$, used in the first assay for the second assay measuring the interaction of His-tagged phage ϕX174 with biotinylated LPSs because both assays involve measuring the interaction of the same phage protein with biotinylated LPSs (claims 1-4, 11, 15) because it is known in the art that calcium

and magnesium bind proteins and both phage ϕX174 and His-tagged phage ϕX174 are equivalent proteins. One of ordinary skill would further recognize that different carriers can be used to immobilize the phage protein in an assay system for measuring the interaction between said phage protein and LPS (claim 4).

As noted above, the "p-12 similar" language has been given its broadest meaning and can therefore, encompass any bacteriophage protein since neither the instant claims nor the specification provide a clear definition of what is meant by "p-12 similar" and it is unclear what Applicants intended to cover by the recitation of "p12-similar" bacteriophage tail protein.

Further, claim 1 has been amended to include the limitation of divalent cations. In view of the amendment, the Suzuki et al. reference is believed to be relevant art.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13-16, 18 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-28 of copending Application No. 10583415 ('415). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the '415 claims are both drawn to a method for detecting endotoxin comprising the steps of incubating a sample with bacteriophage tail proteins immobilized on a surface, and removing and/or detecting the phage tail protein-endotoxin complex by spectroscopic means.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

February 7, 2008

M. Monshipouri
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER